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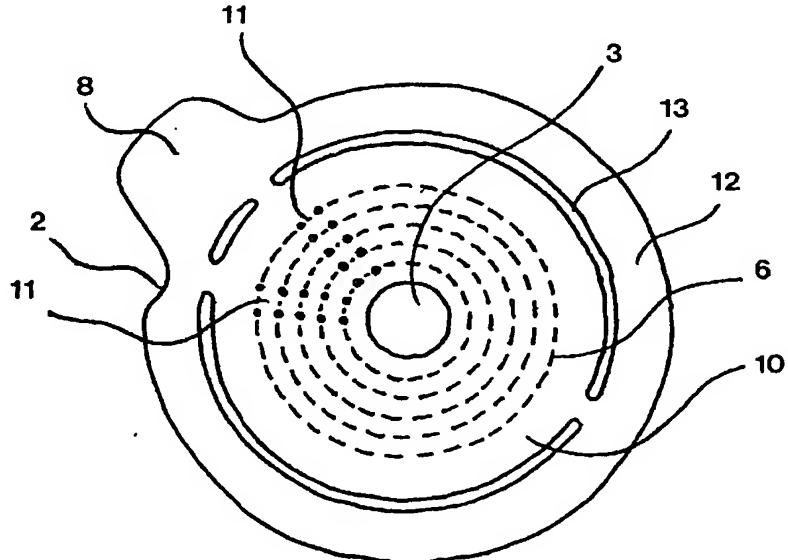
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(54) Title: COLLECTING BAG



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(57) Abstract: A flange for a medical collecting bag having an aperture allowing bodily fluids or exudates to enter the bag, wherein the flange has an inner rim delimiting the aperture therein, and wherein the flange has a central area encircling the aperture which area has a predetermined weakening line pattern wherein the force needed for removing the bag flange from the skin or a body side member is smaller than the force needed for breaking the weakening lines enables a simple gradual enlargement of the aperture of an ostomy device for adaptation of the aperture to the size of the stoma or for adaptation of the aperture to the size of a wound and a complete removal of the bag flange when substituting the bag.



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## COLLECTING BAG

**Field of the Invention**

The present invention relates to a medical appliance comprising a body side member comprising an adhesive wafer for securing the appliance to the patient's skin, said wafer or pad having an aperture allowing bodily fluids or exudates to enter the appliance, and an optionally separately exchangeable collecting bag secured to the body side ostomy member for collecting fluids or excretions.

**Background of the invention**

10 In connection with surgery for a number of diseases in the gastro-intestinal tract a consequence is, in many cases, that the colon, the ileum or the urethra is exposed surgically and the patient is left with an abdominal stoma and the effluents or waste products of the body, which are conveyed through these organs, are discharged through the artificial orifice or opening and are collected in a

15 collection bag, which is usually adhered to the skin by means of an adhesive wafer or plate having an inlet opening for accommodating the stoma. Also in connection with a fistula which has developed between an internal organ and the abdominal surface, the patient will have to rely on an appliance to collect the bodily material emerging from such opening. Collecting bags may also be used

20 for collecting exudates from a wound or collection of bodily material in connection with post operation or drainage purposes.

Such appliances are well known and may be two-piece or one-piece appliances. In both types of appliances, a body side member is attached to the wearer's abdomen, and optionally a collecting member or bag is attached to the body side member for collecting exudates from the stoma or wound in case of a two-piece appliance.

When using one-piece appliances, the whole appliance, including the adhesive wafer or pad securing the appliance to the skin is removed and replaced by a

fresh appliance. When using two-piece appliances, the body side member is left in place for several days, and only the collecting member or bag is replaced.

The service time of the body side ostomy member depends on the amount and aggressiveness of the exudates and of the tightness between the ostomy and

- 5 the body side ostomy member.

#### **Description of the Related Art**

The service time of ostomy appliances may be reduced for several reasons. Due to the aggressiveness of the exudates, the adhesive material of the adhesive wafer may deteriorate and give access to the skin for the exudates. This may

- 10 call for a change of appliance in order to protect the skin. Furthermore, a leakage around the stoma may give rise to appearance of unpleasant materials or odours at the abdomen of the patient which may give rise to skin problems as well as embarrassing situations. In order to increase the service time of especially ostomy appliances it has been proposed to adapt the size of the aperture of the
- 15 adhesive wafer to the size of the actual stoma. One-piece ostomy appliances and body side members of two-piece ostomy appliances are normally offered having adhesive wafers having a range of sizes of apertures for better adaptation to the size of the actual stoma and the adhesive wafer is often provided with a cutting guide typically having series of concentric printed lines having an indica-
- 20 tion of the diameter thereof for facilitating a more accurate customisation using e.g. scissors.

GB Patent Application No. 2 017 501 discloses a device for sealing an ostomy bag to the skin of a patient which device comprises a sheet of material capable of adhering to the skin of a patient and having a slit or cut extending as a spiral 25 or the like. An aperture may then be produced in the sheet by unwinding the coil defined by the slit. The sheet may be of a gelatinous material having a basis of Karaya gum and/or another hydrophilic material.

- The appliances disclosed in GB Patent Application No. 2 017 501 are one-piece appliances.

US Patent No. 3,604,421 discloses a one piece disposable bag having a variable size opening surrounded by separately removable concentric annular strips for forming an opening of variable diameter. However US Patent No. 3,604,421 is silent with respect to the problems associated with removal of all of the bag when

5 substituting the bag.

These two references are silent with respect problems concerning a complete removal of the bag flange of the appliances when substituting the bag and both teach the presence of a central disc to be removed before using the appliance.

In connection with two-piece appliances, the size of the aperture of the collecting

10 bag for receiving a stoma is often greater than the size of the apertures of the commonly used body side members, and there is a considerable risk of access of exudates to the distal surface of the adhesive wafer of the body side member. This opens for chemical attack on the adhesive from the "back" and may furthermore give rise of soiling or contamination the distal surface of the body side

15 member, especially in connection with ileostomies and colostomies. This may reduce the wearing time of the body side member and furthermore give rise to problems when substituting the collecting bag with a fresh as the coupling area may have to be cleaned in order to ensure a proper coupling and sealing of the fresh bag and also to ensure that residues giving rise to unpleasant odours are

20 not left on the body side member. Altogether there is a considerable risk of having to exchange the body side member before its technical service time has been exhausted.

It has been found that these drawbacks may be alleviated by the present invention.

## 25 **Summary of the Invention**

The invention relates in its broadest aspect to a medical appliance comprising a body side member comprising a flange in the form of an adhesive wafer for securing the appliance to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, and an optionally separately

30 exchangeable collecting bag secured to the body side member for collecting

fluids or excretions, wherein the flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern.

The invention further relates to a medical appliance comprising a body side member comprising an adhesive wafer for securing the appliance to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, and a separately exchangeable collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the body side member comprises first coupling means being fixedly connected to the body side member and the collecting bag comprises corresponding second coupling means adapted for releasable coupling and sealing to the body side member, wherein the bag flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern.

5 Furthermore, the invention relates to an ostomy collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the appliance, the bag comprising coupling means for releasable coupling and sealing to corresponding coupling means fixedly connected to a body side member comprising an adhesive wafer for securing the body side member to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the bag flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern.

10 15 Furthermore, the invention relates to an ostomy collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the appliance, the bag comprising coupling means for releasable coupling and sealing to corresponding coupling means fixedly connected to a body side member comprising an adhesive wafer for securing the body side member to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the bag flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern.

20 25 Still further, the invention relates to a flange for a medical collecting bag in the form of a substantially annular flange having an inner rim defining an aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern

**Brief Description of the Drawings**

The invention is described more in detail with reference to the drawings in which

Fig 1 shows an embodiment of a collecting bag according to the invention having a flange having a predetermined weakening line in the form of a helix,

5 Fig. 2 shows a section of the embodiment shown in Fig. 1 along the line A-A,  
Fig. 3 shows the embodiment shown in Fig. 1 seen from the side,  
Fig. 4 shows the embodiment shown in Fig. 1 with a part of the helix detached from the flange,

Fig. 5 shows another embodiment of a flange for a collecting bag according to

10 10 the invention having a predetermined weakening line in the form of concentric lines,

Fig. 6 shows a further embodiment of a flange for a collecting bag according to the invention having a predetermined weakening line in the form of a combination of helical and radial lines,

15 Fig. 7 shows a further embodiment of a collection bag according to the invention having a flange having a predetermined weakening line in the form of a helix and a coupling means,  
Fig. 8 shows a section of the embodiment shown in Fig. 7 along the line B-B, and  
Fig. 9 shows a still further embodiment of a flange for a collecting bag according

20 20 to the invention having a predetermined weakening line in the form of concentric lines.

**Detailed Description of the Present Invention**

The invention relates to a medical appliance comprising a body side member comprising a flange in the form of an adhesive wafer for securing the appliance

25 25 to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, and an optionally separately exchangeable collecting bag secured to the body side member for collecting fluids or excretions, wherein the flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening

30 30 pattern wherein the force needed for removing the bag flange from skin is smaller than the force needed for breaking the weakening lines.

Such an appliance of the invention including a collecting bag as an integral unit (not exchangeable) may be used as a one-piece ostomy appliance or for wound, post operation or drainage purposes offering a simple and effective alleviation of the above-mentioned drawbacks.

- 5 Furthermore, the present invention relates to a medical appliance comprising a body side member comprising an adhesive wafer for securing the appliance to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, and a separately exchangeable collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the
- 10 appliance, wherein the body side member comprises first coupling means being fixedly connected to the body side member and the collecting bag comprises corresponding second coupling means adapted for releasable coupling and sealing to the body side member, wherein the bag flange has an inner rim defining the aperture therein and a central area encircling the aperture which
- 15 area has a predetermined weakening line pattern wherein the force needed for removing the bag flange from the body side member is smaller than the force needed for breaking the weakening lines.

The predetermined weakening line pattern renders it possible to adapt the aperture of a flange of an ostomy collection bag to the size of the actual stoma

- 20 leading to a better protection of the skin or the distal surface of the adhesive wafer of the body side member reducing the contact with the aggressive exudates from a stoma and thus overcoming the above mentioned drawbacks. Furthermore, it is simple to adapt the aperture of the flange by a gradual enlargement for adaptation to the size of the stoma by tearing off a part of the flange
- 25 along the inner rim using the fingers without having to rely on the use of tools.

Usually medical appliances such as ostomy appliances having an adhesive wafer for securing the appliance to a patient's skin are provided with skin-friendly adhesive which is preferably covered by a protecting cover or release liner which may for instance be siliconized paper. It does not need to have the same contour

- 30 as the dressing, e.g. a number of dressings may be attached to a larger sheet of

protective cover. The protective cover is not present during the use of the dressing of the invention. However, in accordance with a preferred embodiment of the invention a protecting cover is present for protecting the adhesive surface before use and during adaptation of the appliance to the individual ostomate.

- 5 The skin-friendly adhesive may be any skin-friendly adhesive known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may e.g. be of the type disclosed in those disclosed in US patent Nos. 4,367,732.

It is preferred according to the invention that there is a difference of the breaking strength of the flange and of the protective cover and that such difference is controlled so as to ensure that the breaking strength of the protective cover is lower than the breaking strength of the flange in order to enable a adaptation of the size of the aperture without removing the release liner. Thus, any unintended contact reducing the binding strength of the adhesive is avoided as is contamination with bacteria. Such difference in breaking strength is preferably obtained by controlling the pattern of weakening lines leaving minor "bridging" areas in the paper than in the flange when producing the weakening lines.

The aperture of the flange of a bag of the invention may thus be adapted to the actual shape of the stoma. This opens for a combination of the desired cleaning effect comparable with the cleaning obtained from the "scraping" against the outer surface of the stoma by the inner rim of the adhesive wafer when exchanging a traditional one-piece ostomy appliance with the advantage of leaving the body side member of a two-piece appliance on the abdomen of the ostomate for a longer span of time.

- 25 When the bag is attached to the body side member, the flange thereof furthermore protects distal surface of the body side member and increases the service time and also reduces the soiling thereof.

The pattern of weakening lines may be any convenient pattern of e.g. in the form of punched or cut dots, slots or interrupted rectilinear or curved lines weakening

the annular flange in a manner enabling removal of parts thereof from the inner rim of the flange. The pattern may be produced using any suitable process known per se for producing such penetrations of a sheet material such as cutting or punching.

- 5 The depth of cuts depends of the nature of the material and may penetrate only partially through the thickness of the flange although it is preferred that it penetrates completely through the flange at the rim of the aperture. It is preferred that weakening line penetrates completely through the thickness of the flange only leaving minor "bridging" areas being easily breakable for enlarging the
- 10 aperture.

In one embodiment of the invention, the weakening pattern is in the form of an interrupted line pattern.

In a preferred embodiment of the invention, the weakening pattern is in the form of an interrupted helical line starting at the inner rim of the flange.

- 15 In another preferred embodiment of the invention, the weakening line pattern is in the form of a number of interrupted concentric lines surrounding the aperture in the second flange.

In a preferred embodiment of the invention, the weakening line pattern is in the form of a combination of helical or concentric lines and radial lines rendering it  
20 easy to adapt to the size and contour of the aperture to the stoma.

It is preferred to provide the outer part of the flange, outside the weakening pattern with perforations in an essentially circular zone corresponding of the kind disclosed in WO 00/30576 for further reducing the risk of leakage due to formation of canals.

- 25 The central area of the flange having an area having a predetermined weakening line pattern may according to another embodiment of the invention show only a weak adhesiveness. Thus, it is preferred that the adhesiveness of the central

area is so weak that the force for removing the flange from the skin or the body side member is smaller than the force needed for breaking the weakening lines.

This renders it possible to ensure a good contact to the skin or the back of the body side member being desirable for protecting the same against soiling and

- 5 also ensures that the bag may be substituted without breaking the remaining weakening lines which may give rise to spilling of waste material situated on the flange inside the bag. In one embodiment of the invention it is ensured that the central area shows very low adhesiveness by utilising a flange having an adhesive having very low tack/peel values and it is also considered an
- 10 embodiment of the invention to provide a flange not having adhesive in the central area. For practical reasons it is often less complicated to apply a layer of adhesive on all of the surface of the flange and then, afterwards to partially or fully disable the adhesive properties in the central area by applying an optionally perforated non-detachable cover layer covering the central area or e.g. by
- 15 covering the adhesive layer of the central area partly or fully with a release agent such as talc. The cuts, dots, slots or interrupted rectilinear or curved lines preferably penetrates a cover layer.

In an especially preferred embodiment of the invention, the weakening pattern of the flange is in the form of concentric lines wherein the weakening pattern has at

- 20 least one interruption in a radial zone from the aperture for receiving the stoma. Along this zone, the tearing resistance is higher than the force necessary for breaking the bridges connecting consecutive rings of the flange. This feature allows for a safe removal of an ostomy collecting bag together with all of the adhesive flange without leaving one or more rings on the body side member. The
- 25 radial direction of such relative enforcement is preferably in the direction of a protruding part or ear facilitating the removal of the bag. In this embodiment, it is not necessary to rely on a weaker adhesiveness in the weakening line area in order to ensure a full removal of the bag and its flange as discussed above.

In another aspect, the invention relates to a medical collecting bag having a bag

- 30 flange having an aperture allowing bodily fluids or exudates to enter the appliance, the bag comprising coupling means for releasable coupling and sealing to corresponding coupling means fixedly connected to a body side

member comprising an adhesive wafer for securing the body side member to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the bag, wherein the bag flange has an inner rim delimiting the aperture therein, and wherein the flange has a central area having a predetermined weakening line pattern wherein the force needed for removing the bag flange from the body side member is smaller than the force needed for breaking the weakening lines.

The coupling means may be any suitable coupling means known per se for coupling of ostomy body side members to ostomy collecting bags, e.g. a

10 mechanical coupling such as matching coupling rings or it may be in the form of a first flange secured to the body side member and a second flange secured to the collecting bag, the second flange being adapted for removable and adhesive coupling and sealing to the first flange. Such second flange is suitably the above mentioned bag flange which then has outer adhesive areas for coupling to the

15 body side member in addition to the central area.

The first and the second flanges are preferably formed as discs of a cellular plastic material, which provides a good shock absorbing and resilient action and also has the effect that the weight of the collecting system can be kept down.

20 In a third aspect, the invention relates to a flange for an ostomy collecting bag having a flange having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the flange has an inner rim delimiting the aperture therein, and wherein the flange has a central area having a predetermined weakening line pattern wherein the force needed for removing the bag flange from the body

25 side member is smaller than the force needed for breaking the weakening lines.

In the present context, the term "distal" in connection with a surface of an appliance is used to designate the surface thereof being opposite to the skin contacting surface thereof.

The term "medical" in connection with a bag or use is used to designate use in connection with collection of bodily fluids or excretions from a surface area or an aperture emerging on the surface of a living being. An appliance according to the invention may thus be a bag for placing on the skin for collecting wound

- 5 exudates, bodily material in connection with post operation or drainage purposes or excretions from the urethra or the intestine which has been lead to an artificial opening in connection with an injure or surgery. A preferred use is for ostomy appliances or wound care appliances, mostly preferred ostomy appliances.

#### Description of the Preferred Embodiments

- 10 Reference is made to Fig. 1 of the drawings showing an embodiment of an ostomy appliance according to the invention. The bag 1 comprises a flange 2 secured to the collecting bag which flange has an inner rim defining an inlet aperture 3 therein for receiving a stoma, and wherein the flange has a central area 4 having a predetermined weakening line pattern 5 in the form of a helical line starting from the inner rim thereof. The collecting bag 1 for collection of materials emerging from the stoma is adapted for coupling to a body side member for securing the bag 1 around the stoma on a patient's abdominal wall. The bag 1 may either be closed as shown or be openable at the bottom for intermittent emptying of its contents. The central area of the flange 2 is in this
- 15 20 embodiment surrounded by a substantially annular part of the flange acting as coupling means for connecting the bag 1 sealingly with a body side member (not shown). Such a body side member comprises a body side member which is designed to be adhered to the patient's skin by means of a skin-friendly adhesive applied on the back of the body side member. The body side member carries
- 25 first coupling means which in connection with this embodiment is in the form of a first flange or body side member flange, in which is formed an aperture and which is designed for receiving an adhesive coupling to the flange 2.

The body side member flange may be secured to the body side member with a layer of adhesive applied in a substantially annular connecting section having an

- 30 internal diameter corresponding to that of the aperture in the body side member flange and having an external diameter so that a rim portion of the flange

protrudes beyond the layer of an adhesive. Of course, the flange may also be secured to the body side member through other means, for example by welding.

The bag flange and a body side member flange may, for example, be moulded in a water-repellent cellular plastics material, such as ethylene vinyl acetate (EVA) 5 or polyurethane (PUR), with closed cells so that the cellular plastic material does not absorb liquid.

The bag itself may be made from any material known per se for the production of ostomy appliances.

On the side facing away from the bag, the flange is coated over substantially all 10 its surface with a thin, washable layer of adhesive (not shown), which may, for example, be a hydrogel adhesive, an acrylate adhesive or an adhesive of the hot-melt type. The layer of adhesive is applied in a thin layer, partly to keep thickness low, and partly to maintain the flexibility and resilience of the bag flange. This application may be effected, for example, by coating, spraying or application 15 in a suitable pattern. When the bag is delivered, the layer of adhesive is covered by a release liner.

The bag flange 2 preferably has a protruding part or ear 8 facilitating the removal of the bag by providing a handle or grip for handling the bag. In such an area, the adhesive is preferably covered by a cover layer.

20 Fig 2 shows a sectional view of the embodiment of a bag of the invention shown in Fig. 2 is taken along the line A-A before preparing the bag for application and indicated the cuts 5.

Fig. 3 shows the same embodiment, seen from the side. In Fig. 4, the bag is being prepared for application and a part 9 of a strip defined by a helical weakening line has been removed from the plane of the flange and is ready for tearing off leaving a bag having an aperture better adapted to the stoma than conventional standardised bags. 25

Fig. 5 shows an embodiment of a flange according to the invention having a weakening line pattern 6 in the form of a number of interrupted concentric lines surrounding the aperture 3 in the flange.

Fig. 6 shows a further embodiment of a flange according to the invention having  
5 a the weakening line pattern 7 in the form of a combination of helical or  
concentric lines and radial lines surrounding the aperture 3 in the flange.

Fig. 7 shows another embodiment of an ostomy appliance according to the  
invention. In this embodiment the bag 1 comprises a flange 2 secured to the  
collecting bag which flange has an inner rim delimiting an inlet aperture 3 therein  
10 for receiving a stoma , and wherein the flange has a central area 4 having a  
predetermined weakening line pattern 5 in the form of a helical line starting from  
the inner rim thereof. In this embodiment, the flange is surrounded by coupling  
means 9 in the form of a coupling ring for connecting the bag 1 sealingly with a  
body side member.  
15 Fig. 8 shows a sectional view of the embodiment of figure 6 along the line B-B  
showing the coupling ring 9 secured to the bag outside the central area.

Fig 9 shows a preferred embodiment of a flange according to the invention. The  
central area of the flange 2 has a weakening line pattern 6 in the form of a  
number of interrupted concentric lines surrounding the aperture 3 and is  
20 surrounded by a substantially annular part 10 of the flange acting as coupling  
means for connecting a bag sealingly to a body side member. The weakening  
pattern has at least one interruption 11 in a radial zone from the aperture for  
receiving the stoma towards the outer periphery and an ear 8 for facilitating the  
removal of the bag. Such relative enforcement may be in the form of an  
25 interruption of the pattern of the weakening line, shown as two sets of "reinforcing  
lines" 11 interrupting the line pattern 6. Outside the annular part 10 is preferably  
an outer part 12 being delimited from the annular part 10 by perforations 13 of  
the kind disclosed in WO 00/30576 in an essentially circular zone for further  
reducing the risk of leakage.

**Claims**

1. A flange for a medical collecting bag having an aperture allowing bodily fluids or exudates to enter the bag, wherein the flange has an inner rim delimiting the aperture therein, and wherein the flange has a central area encircling the aperture which area has a predetermined weakening line pattern wherein the force needed for removing the bag flange from the skin or a body side member is smaller than the force needed for breaking the weakening lines.
2. A flange as claimed in claim 1 wherein the weakening pattern is in the form of an interrupted line pattern.
3. A flange as claimed in claim 1 or 2 wherein the weakening pattern is in the form of punched or cut dots, slots or interrupted rectilinear or curved lines.
4. A flange as claimed in claim 3, wherein the weakening pattern is in the form of an interrupted helical line starting from the inner rim of the flange.
5. A flange as claimed in claim 3, wherein the weakening pattern is in the form of a number of interrupted essentially concentric lines surrounding the aperture of the second flange.
6. A flange as claimed in claim 3 wherein the weakening pattern is in the form of a combination of helical or concentric lines and radial lines.
7. A flange as claimed in claim 3 wherein the weakening pattern is in the form of concentric lines and wherein the weakening pattern has at least one interruption in a radial zone from the aperture for receiving the stoma.
8. A medical appliance comprising a body side member comprising a flange in the form of an adhesive wafer for securing the appliance to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the

appliance, and an optionally separately exchangeable collecting bag secured to the body side member for collecting fluids or excretions, wherein the flange has an inner rim defining the aperture therein and a central area encircling the aperture which area has a predetermined weakening pattern wherein the force

5 needed for removing the bag flange from skin is smaller than the force needed for breaking the weakening lines.

9. An medical collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the appliance, the bag comprising coupling means for releasable coupling and sealing to corresponding coupling means

10 fixedly connected to a body side member comprising an adhesive wafer for securing the body side member to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the bag flange has an inner rim defining the aperture therein and wherein the flange has a central area encircling the aperture and having a predetermined weakening line

15 pattern wherein the force needed for removing the bag flange from the body side member is smaller than the force needed for breaking the weakening lines.

10. An collecting bag as claimed in claim 8 or 9 wherein the central area having a predetermined weakening line pattern does not show adhesive properties.

11. A medical appliance comprising a body side member comprising an adhesive wafer for securing the appliance to a patient's skin, said wafer having an aperture allowing bodily fluids or exudates to enter the appliance, and a separately exchangeable collecting bag having a bag flange having an aperture allowing bodily fluids or exudates to enter the appliance, wherein the body side member comprises first coupling means being fixedly connected to the body side

20 member and the collecting bag comprises corresponding second coupling means adapted for releasable coupling and sealing to the body side member, and wherein the bag flange has an inner rim defining the aperture therein and a central area which area has a predetermined weakening line pattern wherein the force needed for removing the bag flange from the body side member is smaller

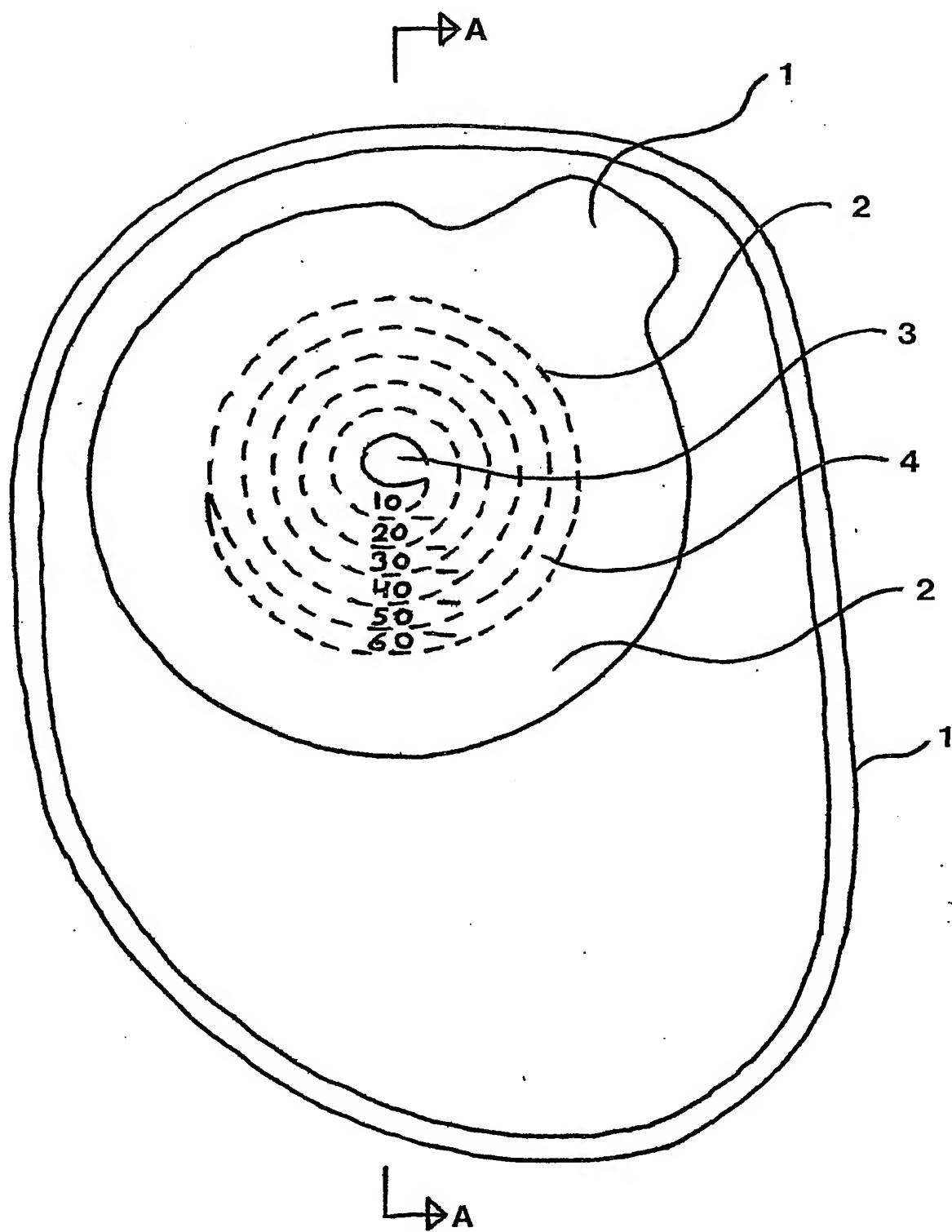
25 than the force needed for breaking the weakening lines.

30

12. An appliance or bag according to any of claims 8 - 11 in the form of an ostomy appliance or bag or a wound care appliance or bag.
13. An appliance or bag as claimed in claim 12 in the form of an ostomy appliance or bag.

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Fig. 1



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Fig. 2

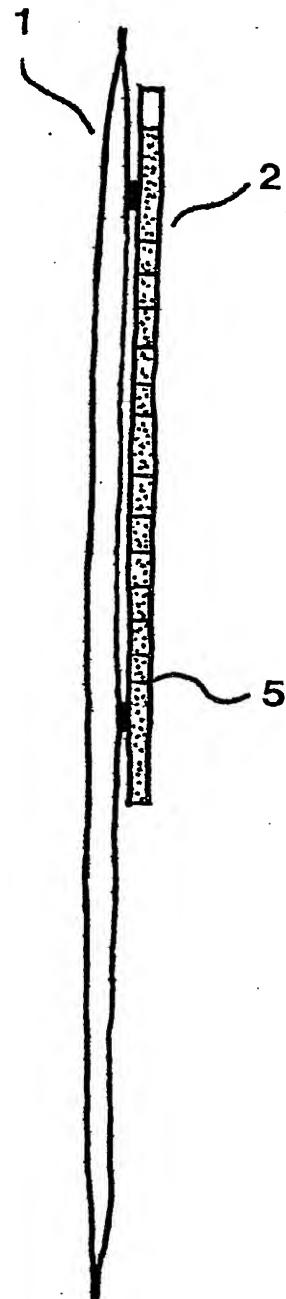
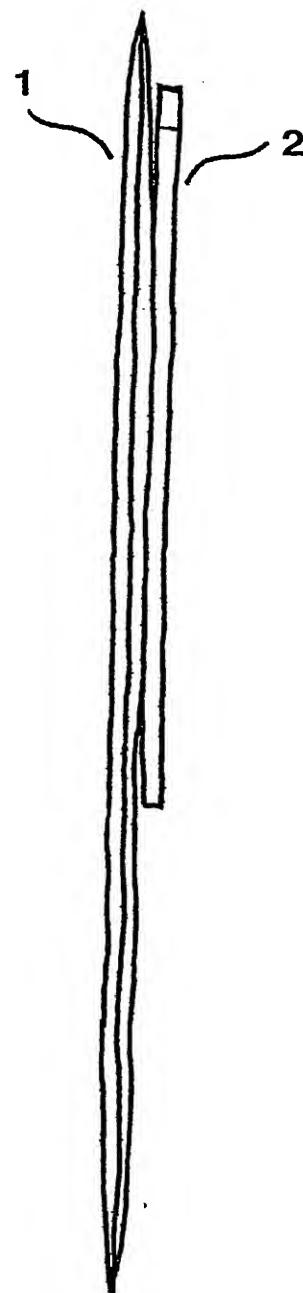
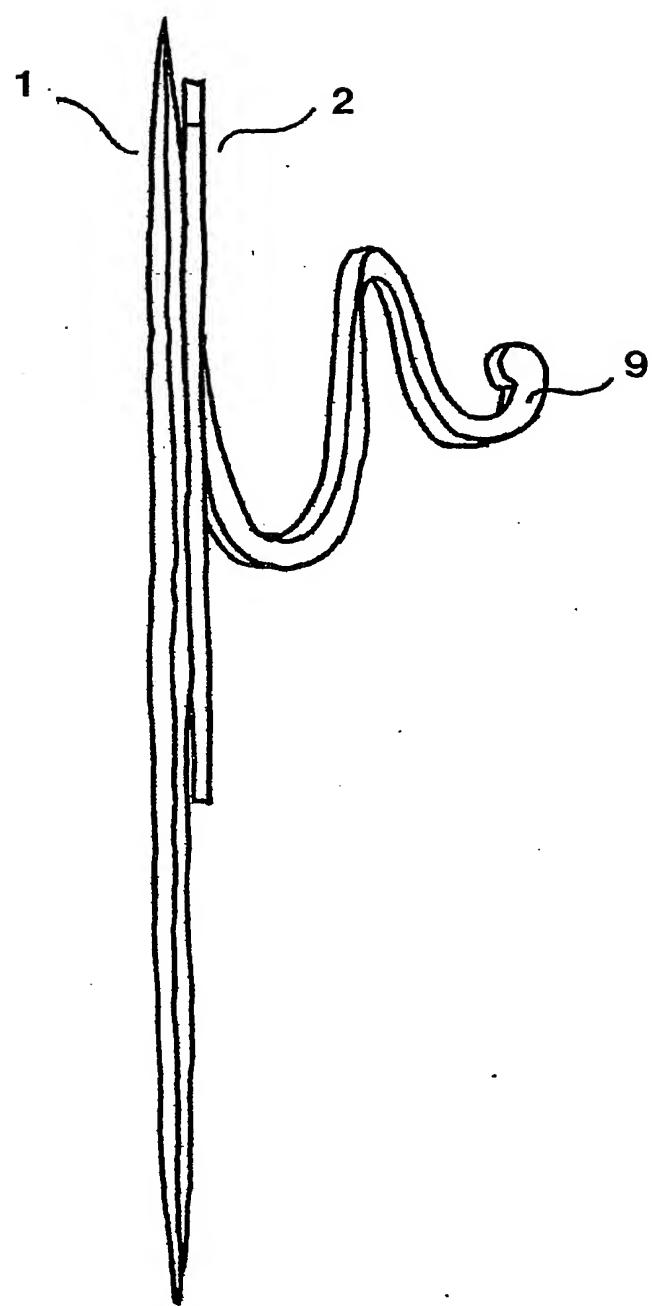


Fig. 3



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Fig. 4



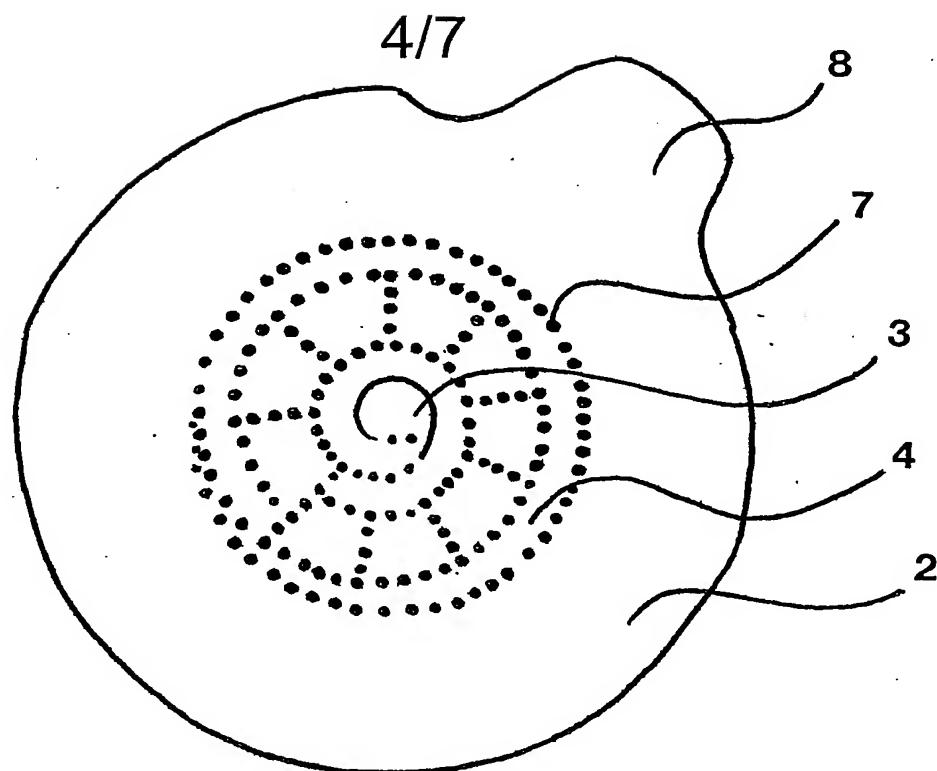


Fig. 6

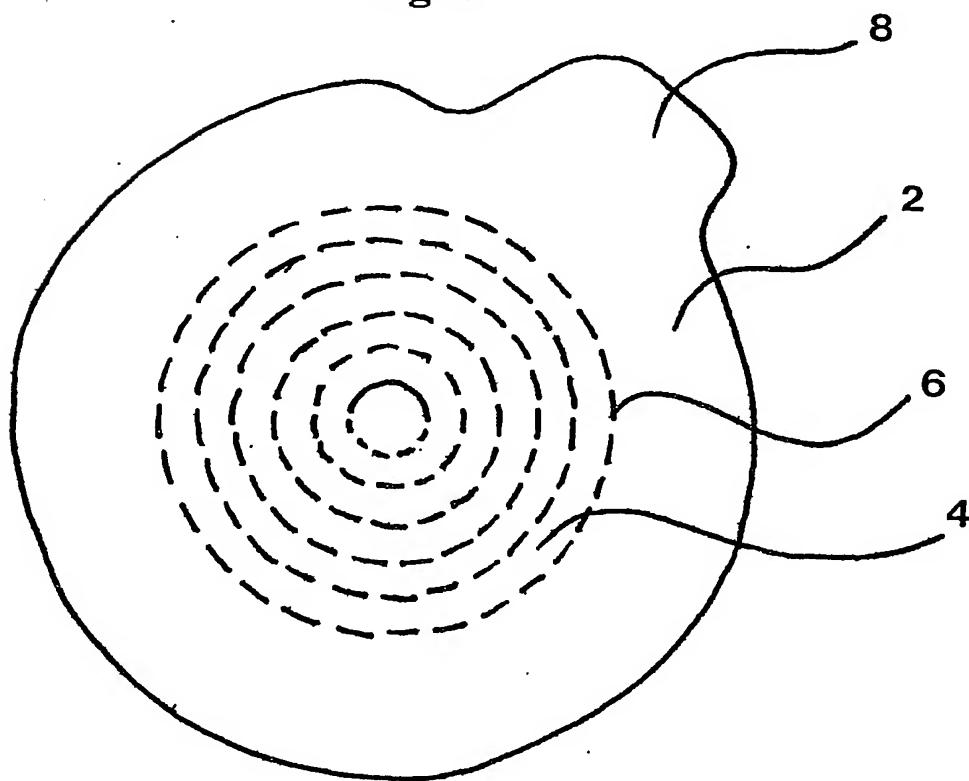
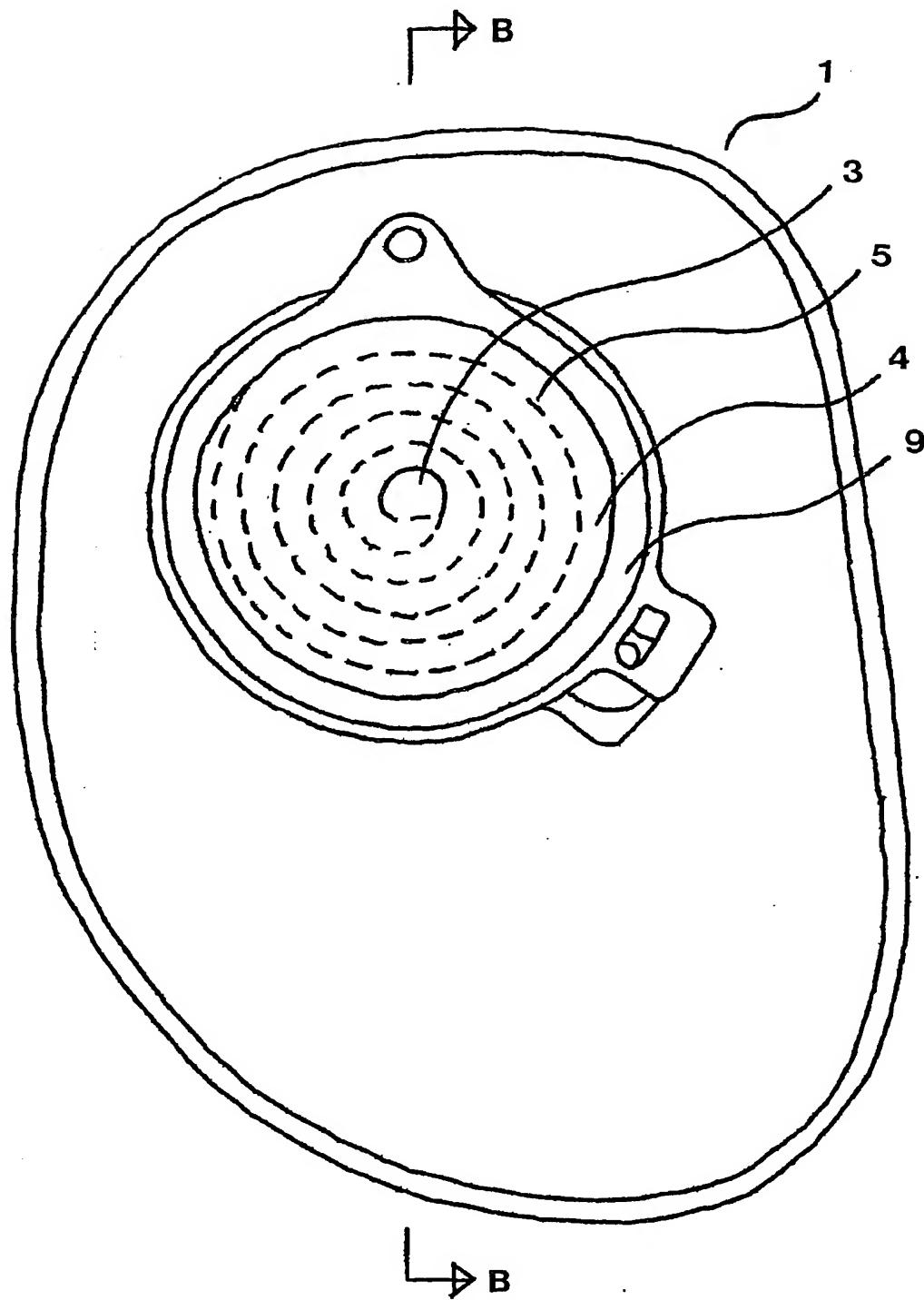


Fig. 5

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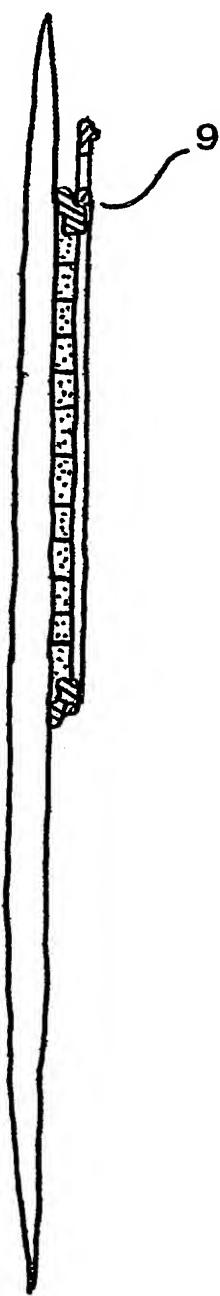
Fig. 7



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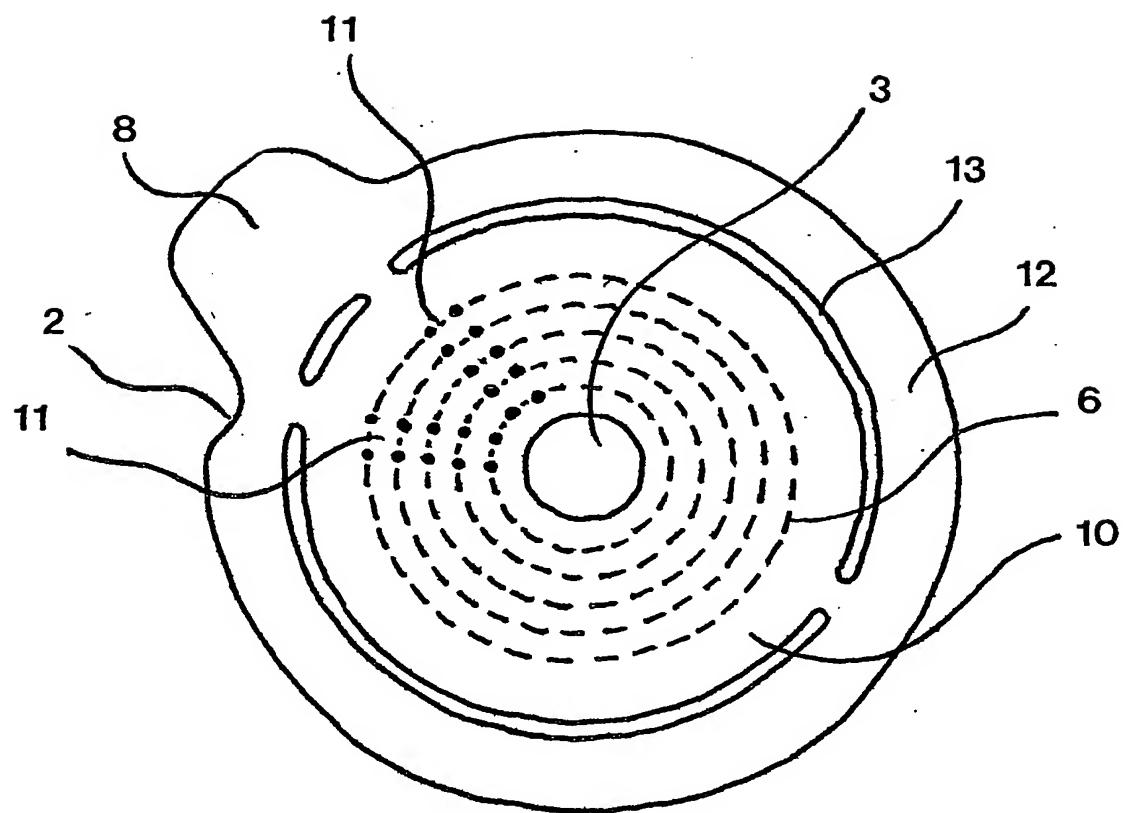
Fig. 8



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Fig. 9



## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/DK 01/00062A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61F5/443 A61F5/448

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 604 421 A (PIZZELLA RAYMOND R) 14 September 1971 (1971-09-14) cited in the application the whole document ---	1-5,8-13
Y	EP 0 276 042 A (CRAIG MED PROD LTD) 27 July 1988 (1988-07-27) abstract; figures 13-18 ---	1-5,8-13
A	GB 2 017 501 A (MATBURN LTD) 10 October 1979 (1979-10-10) cited in the application column 1, line 123 -column 2, line 16; figures ---	1,8,9,11
A	US 4 095 599 A (SIMONET-HAIBE DENISE) 20 June 1978 (1978-06-20) ---	

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21 May 2001

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## INTERNATIONAL SEARCH REPORT

Internat application No  
PCT/DK 01/00062

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 3604421	A	14-09-1971	NONE		
EP 0276042	A	27-07-1988	GB 2157567 A 30-10-1985 AT 50488 T 15-03-1990 AT 72957 T 15-03-1992 AT 72958 T 15-03-1992 AT 71824 T 15-02-1992 AU 581419 B 23-02-1989 AU 3650384 A 27-06-1985 CA 1264134 A 02-01-1990 DE 3481402 D 05-04-1990 DE 3485482 A 05-03-1992 DE 3485548 A 09-04-1992 DE 3485549 A 09-04-1992 DK 83391 A 06-05-1991 DK 608184 A 20-06-1985 EP 0146367 A 26-06-1985 EP 0276043 A 27-07-1988 EP 0276898 A 03-08-1988 GB 2151482 A, B 24-07-1985 GB 2153232 A, B 21-08-1985 IE 56218 B 22-05-1991 JP 1819047 C 27-01-1994 JP 5024781 B 08-04-1993 JP 60156457 A 16-08-1985 JP 1947715 C 10-07-1995 JP 6070950 A 15-03-1994 JP 6071470 B 14-09-1994 NO 845081 A, B, 20-06-1985 NZ 210518 A 08-01-1988 US 4701169 A 20-10-1987 ZA 8409643 A 31-07-1985 GB 2162626 A, B 05-02-1986		
GB 2017501	A	10-10-1979	AU 525363 B 04-11-1982 AU 4530979 A 27-09-1979 CA 1131531 A 14-09-1982 DE 2911314 A 04-10-1979 DK 119079 A 24-09-1979 FR 2420337 A 19-10-1979 IT 1116004 B 10-02-1986 JP 54135492 A 20-10-1979 US 4252120 A 24-02-1981		
US 4095599	A	20-06-1978	FR 2342716 A 30-09-1977 BE 850153 A 06-07-1977 BR 7700649 A 04-10-1977 CA 1098002 A 24-03-1981 CH 610519 A 30-04-1979 DE 2703032 A 25-08-1977 DK 68077 A 19-08-1977 ES 225569 Y 01-07-1977 GB 1521796 A 16-08-1978 IT 1083451 B 21-05-1985 JP 1123148 C 12-11-1982 JP 52100796 A 24-08-1977 JP 57015893 B 01-04-1982 LU 76528 A 18-09-1978		

## INTERNATIONAL SEARCH REPORT

Internal Application No  
PCT/DK 01/00062

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 4095599	A	MX	143096 A	13-03-1981
		NL	7701220 A, B,	22-08-1977
		SE	424261 B	12-07-1982
		SE	7701721 A	19-08-1977
		YU	43377 A	31-05-1982